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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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In re application of  
Nakayuki YAMAMOTO et al.

Serial No. 08/913,056

Appeal No. #18

Filed October 22, 1997

(GROUP 1617)

MUCOSAL PREPARATION CONTAINING  
PHYSIOLOGICALLY ACTIVE PEPTIDE

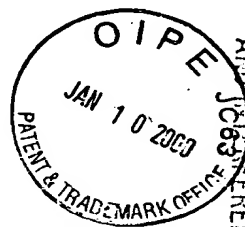
REPLY BRIEF

MAY IT PLEASE YOUR HONORS:

This responds to the Examiner's Answer mailed  
November 8, 1999.

The Examiner seems to recognize that, if appellants are correct in their assertion that the primary reference to MASIZ 5,645,854 teaches a composition contemplated solely for transdermal administration, then there could have been no motivation to replace the irritant vasodilators of the primary reference with suitable vasodilators for transmucosal administration such as those exemplified in the secondary reference to ROBERTS et al. 5,750,141, and further to replace the transdermal permeation enhancers of MASIZ with any of the transmucosal absorption promoters of the remaining five secondary references.

The Examiner's continuing defense of the rejection on appeal is based on an effort to read MASIZ as teaching other than transdermal delivery of the disclosed composition. That effort plainly fails. The Examiner's position is based solely on the disclosure at column 5, lines 19-28 of the



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reference, and in particular on the laundry list of bodily fluids set forth at column 5, lines 25-28.

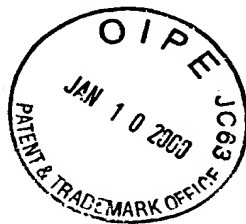
The fundamental flaw in the Examiner's analysis in this respect, however, is that the list of bodily fluids set forth at column 5, lines 25-28 of MASIZ simply bears no relation to the delivery route of the disclosed composition, which the entire remainder of the reference emphatically describes as being solely transdermal. Instead, the bodily fluids at column 5, lines 25-28 of the reference are described as being those which dissolve the water soluble gum that binds the MASIZ composition together, to form the "MULE" complex described by the reference. The "MULE" complex is disclosed as being the transdermal transport vehicle, such that exposure to any member of the list of bodily fluids at column 5, lines 25-28 of the reference, serves to destroy the transport vehicle and render the composition unsuited for administration by any route. In other words, the list of bodily fluids at column 5, lines 25-28 of the reference come into play only after the MASIZ composition has been transported transdermally, which, again, is the sole route of administration contemplated by the reference.

In the bottom of page 4 of the Examiner's Answer, the Examiner appears to inadvertently mischaracterize appellants' statement that transdermal delivery is through nasal or rectal mucosal tissue; instead, we believe that the Examiner intended to characterize the appellants' argument as it relates to the conventional manners of transmucosal

delivery. That the claims on appeal are not limited to administration through nasal or rectal mucosal tissue does not alter the fact that, as demonstrated above, the applied combination of references does not render *prima facie* obvious the claimed compositions in the first instance.

The Examiner's newly-placed (and belated) reliance on the mention of mucoid secretions at column 5, line 25 of the reference does nothing to improve the rejection, but rather underscores the impropriety of the rejection. Given that mucoid secretions are acknowledged by MASIZ as breaking down the transport vehicle described by the reference, it is clear that the compositions of the reference are unsuited for transmucosal administration, because by the very terms of the reference, the transport vehicle would be destroyed before it had the opportunity to pass through such tissue.

We believe that the above discussion, when considered together with the arguments made in the main Brief on Appeal filed August 10, 1999, further demonstrates that the



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rejection on appeal is improper and must be reversed. Such action is respectfully requested.

Respectfully submitted,

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